2015-1950, 2015-1967

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

U.S. WATER SERVICES, INC. AND ROY JOHNSON,
Plaintiffs–Appellants,

v.

NOVOZYMES A/S AND NOVOZYMES NORTH AMERICA, INC.,
Defendants–Cross-Appellants.

Appeal from the United States District Court for the Western District of Wisconsin in case no. 3:13-cv-00864-jdp, Judge James D. Peterson

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NON-CONFIDENTIAL PLAINTIFFS-APPELLANTS' REPLY ON DIRECT APPEAL AND RESPONSE ON CROSS APPEAL

John S. Skilton
David J. Harth
Michelle M. Umberger
Autumn N. Nero
Brandon M. Lewis
PERKINS COIE LLP
1 East Main Street, Suite 201
Madison, Wisconsin 53703-5118
Phone: (608) 663-7460
E-mail: MUmberger@perkinscoie.com

Colin G. Sandercock
PERKINS COIE LLP
700 Thirteenth Street N.W.
Suite 600
Washington, DC 20005
Phone (202) 654-6200
Email: CSandercock@perkinscoie.com

Attorneys for Plaintiffs-Appellants U.S. Water Services, Inc. and Roy Johnson

January 28, 2016

CERTIFICATE OF INTEREST

Counsel for appellants U.S. Water Services, Inc. and Roy Johnson certify the following:

The full name of every party represented by me is:

U.S. Water Services, Inc. and Roy Johnson

The names of the real parties in interest represented by me are:

U.S. Water Services, Inc. and Roy Johnson

The names of all parent corporations and any publicly held companies that own 10% or more of the stock of U.S. Water Services, Inc. represented by me are:

Allete, Inc.

The names of all law firms and the partners or associates that appeared for the party or amicus curiae now represented by me in the trial court or are expected to appear in this Court are listed below.

PERKINS COIE LLP

Emily J. Greb	David J. Harth	Lissa R. Koop
Brandon M. Lewis	Autumn N. Nero	Anne M. Readel*
Joseph W. Ricigliano	Colin G. Sandercock	John S. Skilton
Michelle M. Umberger		

Dated: January 28, 2016

/s/ Michelle Umberger
Michelle M. Umberger

* No longer with the firm

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Caransa	U.S. Patent No. 4,914,029 to Abraham Caransa et al. (A3114-19)
Novozymes	Defendants-cross-appellants Novozymes A/S and Novozymes North American, Inc.
Order	The district court's July 29, 2015 summary judgment order, ECF No. 561 (A2-37).
S.J. Opp'n	Plaintiffs' Opposition to Novozymes' Motion for Summary Judgment, ECF No. 226 (A1636-1823)
S.J. Mem.	Memorandum in Support of Plaintiff's Motion for Summary Judgment, ECF No. 204 (A5501-5637)
Br.	Confidential Principal and Response Brief of Defendants–Cross-Appellants Novozymes A/S and Novozymes North American, Inc. (ECF No. 13)
Veit	World Intellectual Property Application No. WO 2001/62947 to Chris Veit et al. (A1581-1610)
U.S. Water	Plaintiffs-Appellants U.S. Water Services, Inc. and Roy Johnson
U.S. Water Br.	Corrected Nonconfidential Brief of Plaintiffs Appellants, ECF No. 35
'137 patent	United States Patent No. 8,415,137 (A134-42)
'244 patent	United States Patent No. 8,039,244 (A1345-53)
'399 patent	United States Patent No. 8,609,399 (A143-52)
'### patent (xx:yy-zz)	Column xx, lines yy to zz of the '### patent

REPLY ON DIRECT APPEAL

I. The District Court's Grant of Summary Judgment of Inherent Anticipation Was Factually and Legally Erroneous.

The district court granted summary judgment despite finding that U.S. Water had presented evidence that the teachings of the prior art "will not *always* result in deposit reduction." A28 (emphasis in original). The district court, however, deemed this evidence "not relevant" because it is "immaterial whether one skilled in the art would practice Veit and Antrim for the *purpose* of combating fouling …." A28-29 (emphasis in original). But U.S. Water has never maintained that anticipation requires that one of ordinary skill appreciate that a particular limitation is present in the prior art or that the discovery of a new benefit from an old process is patentable. *See, e.g.*, U.S. Water Br. at 36 ("[T]his Court's precedent … [holds] that a new goal or precedent, on its own, will not salvage an otherwise anticipated claim where the prior art inherently practiced all limitations of the invention."). The district court erred in applying the law of inherent anticipation, an error Novozymes urges this Court to repeat.

By focusing on the purpose or object of the prior art, the district court never directly addressed the critical factual question presented by Novozymes' claim of inherency—whether the practice of Veit or Antrim *necessarily* or *inevitably* results in deposit reduction. Had the district court addressed this question, it could only have concluded that there was a sharp disagreement between the parties and their experts. It was error to resolve this factual dispute on summary judgement.

A. The fact that phytase hydrolyzes phytic acid does not mean it necessarily reduces deposit formation under all conditions.

Further muddying the water was that instead of determining whether the result of the patented method (deposit reduction) was inherent in the prior art, the district court became distracted by an irrelevant issue—whether the chemical reaction disclosed in the prior art and the asserted patents is the same. This too was error.

The district court placed great weight on testimony from both sides' experts that, by definition, phytase "hydrolyzes," or "breaks down" phytic acid. *See* A27 ("The undisputed evidence establishes that Veit, Antrim and the patents-in-suit disclose the same chemical process through which phytase breaks down phytic acid."); A32 ("The patents-in-suit describe a method for using phytase to break down phytic acid; so do Veit and Antrim."). Novozymes (and the district court) reasoned from this premise that because "the parties' experts agree that phytase will degrade phytic acid under the process conditions disclosed by Veit, Antrim, and the asserted patents … *as a result*, fewer deposits of phytic acid salts will form." Br. at 33 (emphasis added). But, the one does not follow from the other, and although the parties do not dispute that phytase hydrolyzes phytic acid (a law of nature), the parties *do* dispute whether the addition of phytase to ethanol processing fluids will necessarily and inevitably result in deposit reduction. U.S. Water's evidence that it does not—which the district court failed to address—included the teachings of the asserted patents and the testimony of qualified experts on the kinetics of deposit reduction.

1. The patents-in-suit teach that deposit reduction will only occur under certain conditions.

The U.S. Water patents expressly teach that numerous parameters can effect on whether deposit reduction occurs:

> In an embodiment, the present invention provides a method in which the agent or enzyme is introduced into the ethanol processing fluid under optimal conditions of temperature and pressure. Where the agent is phytase, the term "optimal conditions" refers to those conditions of concentration, temperature, residence time or reaction time, and pH that allow sufficient reaction with soluble phytate, phytate suspension, phytate precipitate, or insoluble phytate scale that reduces the level of the phytase deposit to an amount acceptable for operation of the ethanol plant or process.

'137 patent (6:29-38); *see also* '399 patent (same). Thus the asserted patents recognize that deposit reduction will be affected by parameters such as temperature, residence time, and pH. Likewise, the patents teach that enzyme concentration and residence time also can have substantial effects on deposit reduction. '137 patent (7:1-50); *see also* '399 patent (same).

Indeed, Novozymes acknowledges that the asserted patents teach the necessity of adding phytase under optimal conditions when it argues that the claims of those patents are invalid for lack of enablement. According to Novozymes, one of ordinary skill would not be able to determine the conditions required for deposit reduction without undue experimentation. Br. at 49-52. But if this is the case, deposit reduction cannot be said to be inherent in the mere act of adding phytase to ethanol processing fluids under any and all conditions, particularly the ranges of conditions disclosed in Veit and Antrim.[1]

The U.S. Water patents teach a skilled artisan that adding phytase to ethanol fluids will only reduce deposits under certain conditions. Thus, one of ordinary skill would not expect that the addition of phytase under the broad range of conditions disclosed in Veit and Antrim would reduce phytic acid deposits. It is simply untrue, as Novozymes argues, that "[t]he specification of the asserted patents makes clear that deposit reduction is merely the natural result of breaking down phytic acid in ethanol processing fluid by adding phytase." Br. at 31. Indeed, the specification teaches just the opposite: in order to reduce deposits, the phytase must be added under "those conditions of concentration, temperature, residue time or reaction time and pH that allow sufficient reaction with [phytic acid] that reduces the level of phytase deposit …." '137 patent (6:33-37); '399 patent (same). Likewise, Veit and Antrim will only achieve deposit reduction if practiced

[1] Novozymes' failure to support its nonenablement position with evidence that the amount of experimentation required to achieve deposit reduction is anything other than routine is discussed below, *infra*, Part II.A.4.

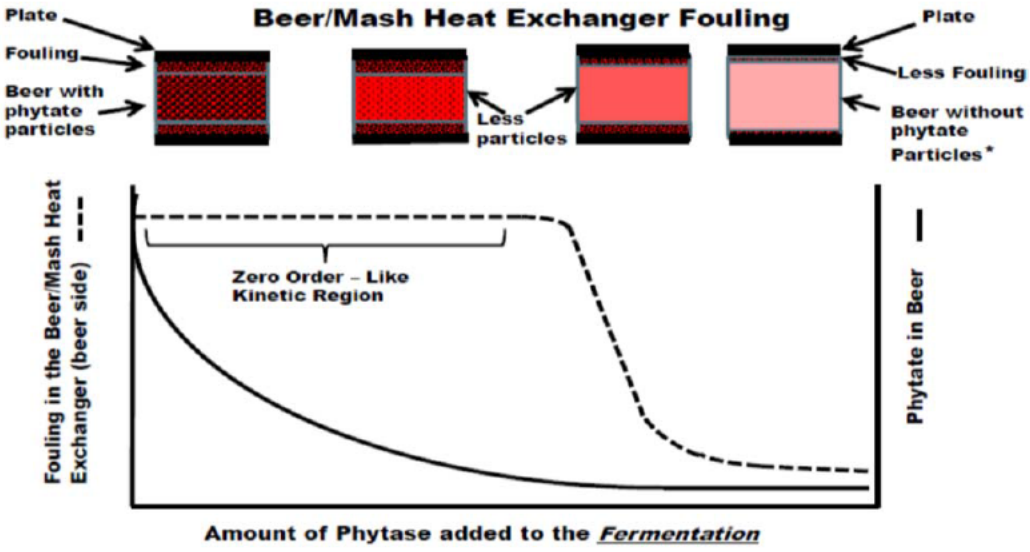
under the same conditions and will *not* achieve deposit reduction if those conditions are unmet.

2. Both sides' experts acknowledged that various reaction conditions affect the ability of phytase to reduce deposits.

U.S. Water's experts both testified that merely adding phytase to ethanol production fluids will not necessarily reduce deposit formation. Dr. Reed, a professor of enzyme chemistry at the University of Wisconsin, identified a number of factors "that can impact the ability of phytases to convert phytic acid to its hydrolysis products during ethanol processing." A760 (¶ 31). Among them are many of the same conditions identified in the specification of the U.S. Water patents, including temperature (A755-57 (¶¶ 19, 22-23)), pH (A757 (¶ 24)), and reaction time (A757-58 (¶ 25)).

Mr. Dorn, a chemical engineer with extensive experience working in fuel ethanol plants, provided testimony, summarized in U.S. Water's opening brief, that the formation and reduction of phytic acid deposits on heat transfer surfaces depends on "zero order kinetics," which means that one can remove substantial amounts of the phytic acid in a plant and still not reduce fouling. U.S. Water Br. at 14-16; *see also* A850-60 (¶¶ 40-63).

As explained by Mr. Dorn, merely adding phytase to a fuel ethanol plant will not necessarily lead to a reduction of phytic acid deposits. A5725 (¶ 14). Indeed, there will be no reduction in fouling until the amount of phytic acid in the ethanol processing fluid is reduced to the point where most of the insoluble phytic acid in the system is gone and largely only the soluble phytic acid remains. A5728 (¶ 23). Only at this point, described by Mr. Dorn as a "switch" or a "cliff," does deposit reduction take place, as illustrated by the following graph:


Beer/Mash Heat Exchanger Fouling
Plate
Fouling
Beer with phytate particles
Less particles
Plate
Less Fouling
Beer without phytate Particles*
Fouling in the Beer/Mash Heat Exchanger (beer side)
Zero Order – Like Kinetic Region
Phytate in Beer
Amount of Phytase added to the Fermentation

*The intensity of red in the beer show the level of soluble phytate, pink indicates sub-saturating amounts of phytate and essentially no phytate particles

A5728-29 (¶¶ 23-24); A5737 (App. 2).[2]

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2 REDACTED [redacted]

Even Novozymes' expert Dr. Kohl agreed that the ability of phytase to reduce deposits depends on a number of "variables," including the amount and type of phytase added, temperature and cook time, grain source and grind size:

> Q. Hypothetically, if you add enough phytase to remove 10 percent of the phytic acid in beer, will you necessarily decrease deposits?
>
> * * *
>
> A. Within the ability to measure you may not see a reduction, but there is necessarily less phytate to form deposits and adhere to deposits.
> Q. How much of the phytic acid do you have to remove before you will get a measurable reduction in deposits?
>
> * * *
>
> A. There are a number of variables that are responsible for deposits. Without going through those variables and fixing them at a particular site knowing where the system was before, where the system is now, I cannot speculate on the amount required to see a measurable change.
> Q. Well, one variable would be the amount of phytase that was added, correct?
> A. Yes.
>
> * * *
>
> Q. What would the other variables that you just mentioned be?
> A. Another variable would be temperature of cook.
> Q. Any others?
> A. Another variable would be source of grain.
> Q. Any more?

A. Another variable would be the grind size used in the facility.

* * *

Q. What about the type of phytase?
A. The type of phytase will be a variable.

A5662-63 (97:14-101:10).[3]

Thus, Dr. Kohl admits in his deposition testimony that there are a number of "variables" that will impact whether phytase will reduce deposits. For that reason, a skilled artisan could practice Veit or Antrim without reducing deposits, an express limitation of each asserted claim of the U.S. Water patents.

The district court erred when it based its grant of summary judgment on some perceived agreement among the parties' experts concerning the chemical properties of phytase. The real question is whether the addition of phytase to ethanol processing fluids necessarily and inevitably reduces deposits. The experts' conflicting opinions on this critical issue do not evidence agreement, but a genuine dispute of material fact not resolvable on a paper record.

[3] Although Dr. Kohl gave his deposition after the close of briefing on Novozymes' summary judgment motion, his admissions would have been admissible as impeachment at trial. In its opening brief, Novozymes seeks to impeach Mr. Dorn with his deposition testimony, also taken after the close of summary judgment briefing. Br. at 41.

B. *King Pharmaceuticals* is readily distinguishable from the facts in this case.

Novozymes relies on *King Pharmaceuticals, Inc. v. Eon Laboratories, Inc.*, 616 F.3d 1267 (Fed. Cir. 2010), for the proposition that the teaching of the U.S. Water patents and the testimony of U.S. Water's experts concerning the optimal conditions required for deposit reduction can be ignored in determining inherency, because these teachings are "unclaimed features" of the invention. Br. at 34-39. *King Pharmaceuticals* does not so hold.

But, *King Pharmaceuticals* does not limit this Court to a sterile examination of the asserted patents' claim limitations without reference to the specification. In *King Pharmaceuticals* the Court reviewed the asserted patent's specification and found, unlike in this case, that the specification did not teach the limiting conditions claimed by the patentee. 616 F.3d at 1275 ("[t]he written description in no way suggests that the specific food conditions disclosed were necessary for increasing metaxalone's bioavailability").

In this case, the specification of the U.S. Water patents devotes two columns to explaining the various parameters that can affect the ability of a phytase to reduce fouling. *See* '137 patent (6:10-28 (addition point), 6:41-48 (temperature), 6:48-54 (pH), 6:55-67 (concentration), 7:1-50 (concentration and reaction time), 7:51-8:15 (temperature and pH)). Conversely, because they are not concerned with deposit reduction, Veit and Antrim say nothing about which conditions are required to achieve such reduction.

Unlike *King Pharmaceuticals*, where the court found that the preamble was the source of novelty, the asserted patents all contain an express limitation that the addition of phytase achieves a reduction in the formation of deposits. *See, e.g.*, claim 1 of the ’399 patent (“wherein providing the additive comprising phytase in the ethanol processing fluid causes a reduction of the formation of insoluble deposits of phytic acid and/or salts of phytic acid in a piece of heat transfer equipment in the plant”). The asserted claims do not merely recite the step of adding phytase; the claimed step of adding phytase specifically requires a reduction in the formation of deposits.

Notably, *King Pharmaceuticals* cites with approval *In Re Oelrich*, 666 F.2d 578, 582 (C.C.P.A. 1981), which rejected an inherent anticipation defense where the missing limitation was not “inevitably present” in the prior art. Something is “inevitable” when it is “certain to happen.” *New Oxford American Dictionary* 888 (3d ed. 2010). Here, U.S. Water adduced substantial evidence that deposit reduction is *not* certain to happen under the broad range of conditions disclosed by Veit and Antrim, because, among other things, the “cliff effect” prevents deposit reduction until enough phytic acid has been hydrolized. This key fact distinguishes the case from *King Pharmaceuticals*, where there was no dispute but that “the increase in metaxalone's bioavailability is the natural result flowing from the [prior art's] explicitly explicated limitations." 616 F.3d at 1276 (citation omitted).

That *King Pharmaceuticals* was decided on its facts and did not change the law of inherency is demonstrated by a more recent case, *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952 (Fed. Cir. 2014), *cert. denied*, 135 S. Ct. 956 (2015). There, Allergan sought to enforce a patent on the use of a bimatoprost ophthalmic solution to treat hypotrichosis (hair loss or reduction) of the eyelashes by stimulating hair growth. 754 F.3d at 955. Apotex contended that a prior art patent on using eyedrops containing bimatoprost to treat glaucoma inherently anticipated the patent-in-suit because often, during the course of treatment with the bimatoprost glaucoma drops, excess fluid comes into contact with the eyelid, which promotes hair growth. *Id.* at 960. Indeed, the ability of bimatoprost to promote eyelash growth was discovered in the course of clinical trials of the glaucoma drops. *Id.*

Nonetheless, although there was no dispute "that the application of eyedrops containing bimatoprost *can* result in the promotion of eyelash hair," that was not enough. *Id.* at 960 (emphasis in original). Because the district court found "that it was at least *possible* to administer eyedrops in a way" that would not result in the promotion of eyelash grown, this Court affirmed the district court's rejection of Allergan's anticipation defense.[4] *Id.* (emphasis in original).

C. Novozymes' attempt to impeach Mr. Dorn's opinions only highlights the need for trial.

Novozymes seeks to discredit the opinions offered by U.S. Water expert Eric Dorn concerning the zero order kinetics or "cliff effect" of deposit control. Br. at 39-42. According to Novozymes, Mr. Dorn's opinions are only a "theory" and "somewhat difficult to understand," and "[n]owhere does Mr. Dorn demonstrate that phytic acid deposits actually behave in the way he contends …." *Id.* at 41.[5] But this sort of argumentation is not a basis for summary judgment, at best it can serve as fodder for cross-examination at trial. As this Court held in reversing another grant of summary judgment of inherent anticipation in the face of conflicting expert testimony:

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[4] It is noteworthy that the district court's findings on the inherency issue came after a trial at which Apotex's expert witness "persuasively testified" that a properly applied drop would not necessarily come into contact with the skin. *Id.* at 960. Because the case was decided on summary judgment, the finder of fact in this case did not have the same opportunity to evaluate the parties' competing experts and to observe them under cross-examination.

[5] U.S. Water disagrees. *See, supra*, Part I.A.2. Regardless, the charge that Mr. Dorn's opinions are "unsubstantiated" more appropriately can be leveled at Novozymes' Dr. Kohl, who conducted no empirical testing in support of his inherency theories:

> Q. Have you done any empirical work to document that there has been a reduction in deposits at the dosages that are listed on your chart?
>
> MR. TELLEKSON: Objection, vague as to empirical -- or evidence.
>
> Q. Have you done any measurements, have you done any inspections, have you done any sort of testing?
>
> A. I have not.

A5659 (88:12-19).

> Where there is a material dispute as to the credibility and weight that should be afforded to conflicting expert reports, summary judgment is usually inappropriate. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1578 (Fed. Cir. 1991) ("To the extent that apparent inconsistencies among the [expert's] three declarations raise questions of credibility and weight … they were improperly resolved on summary judgment.").

Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp., 635 F.3d 1373, 1384 (Fed. Cir. 2011); *see also Metro. Life Ins. Co. v. Bancorp Servs., L.L.C.*, 527 F.3d 1330, 1338-39 (Fed. Cir. 2008) ("There was thus a direct conflict in the [expert] declarations as to a material fact …. The district court dismissed this conflict by crediting the MetLife declarations. Resolving such credibility disputes, however, is not appropriate on summary judgment."); *Veolia Water Solutions & Techs. N. Am., Inc. v. Aquatech Int'l Corp.*, No. CIV. A. 10-484, 2015 WL 4863594, at *23 (W.D. Pa. Aug. 13, 2015) ("The remainder of Aquatech's motion amounts to an argument that Veolia's expert (Cohen) is wrong, and Aquatech's expert (Goodloe) is right …. A disagreement between expert witnesses is precisely a circumstance that prevents entry of judgment as a matter of law.") (citing *B-K Lighting, Inc. v. Fresno Valves & Castings, Inc.*, 375 F. App'x 28, 32 (Fed. Cir. 2010); *Metro. Life*, 527 F.3d at 1338-39).

Moreover, because the district court based its decision only on the basic chemical reaction caused by adding phytase to ethanol production fluids and ignored the critical question of whether adding phytase necessarily and inevitably causes deposition reduction, the district court did not address Mr. Dorn's opinions on how zero order kinetics functions to limit the reduction of such deposits. Should this Court agree that the operative question is whether adding phytase necessarily and inevitably causes deposition reduction, then Mr. Dorn's opinions should be considered in the context of a trial on the merits.[6]

D. Novozymes' "practicing the prior art" defense, if accepted, would turn this Court's inherency jurisprudence on its head.

Novozymes does not dispute that, before it began its infringing activities, there is no evidence that any fuel ethanol plant ever practiced Veit or Antrim, let alone achieved deposit reduction from doing so. Br. at 42-44. But, argues Novozymes, because U.S. Water maintains that Novozymes' customers directly infringe the U.S. Water patents, "U.S. Water effectively admits inherency by accusing the named plants of infringement." *Id.* at 43. This argument does not withstand analysis.

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[6] Pending, but undecided in light of the district court's grant of summary judgment, was Novozymes' motion *in limine* to strike Mr. Dorn's testimony for essentially the reasons argued in its brief on this appeal. A114 (Docket Sheet at ECF No. 443). Needless to say, U.S. Water has opposed the motion. A122 (Docket Sheet at ECF No. 500).

In fact, the opposite of this argument is true. Each independent claim of the asserted patents requires that the addition of phytase to ethanol processing fluid "reduc[e] the formation of deposits" ('137 patent, claim 1) or "causes a reduction of the formation of insoluble deposits" ('399 patent, claims 1, 2, 25, and 34). Novozymes disputed that the accused plants met these deposit reduction limitations, even when its Phytaflow® product was added within the ranges disclosed by Veit and Antrim.[7] But if adding Phytaflow®, a phytase, in accordance with the prior art, does not result in deposit reduction, then such reduction cannot be said to be inherent in that prior art.

More fundamentally, Novozymes' "practicing the prior art" defense is antithetical to the basic law of inherency. Under Novozymes' theory, if even one in a hundred practitioners achieved a particular result, a finding of inherent anticipation would be required, because that lone example could be said to be "practicing the prior art." Br. at 47. But inherency requires that the prior art "certainly and necessarily" produce the missing limitation. And even Novozymes acknowledges that inherency may not be established by "probabilities or

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7 REDACTED [redacted]

possibilities." *Id.* at 30. This Court has held that if it is even possible that the prior art method will not produce that result, there can be no inherency. *Allergan*, 754 F.3d at 960; *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047-48 (Fed. Cir. 1995) (process that yielded claimed compound most, but not all of the time, did not inherently anticipate). And as shown in this and U.S. Water's opening brief, there is a genuine dispute of material fact whether the prior art necessarily meets the deposit reduction limitation of the U.S. Water patents that is admittedly missing from the prior art.

II. Novozymes' "Alternative Grounds" for Affirmance Also Turn on Disputed Issues of Material Fact.

Novozymes asserts (Br. at 48-56) as alternative grounds for affirmance (i) lack of written description and enablement and (ii) obviousness. The district court addressed neither issue. Accordingly, this Court has discretion to not consider these defenses until the district court has had an opportunity to do so. *See, e.g.*, *Hydril Co. LP v. Grant Prideco LP*, 474 F.3d 1344, 1351 (Fed. Cir. 2007) (declining to consider additional grounds for affirmance in part as their "answers may require careful study of an already substantial record or even augmentation of that record"); *Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 573 (Fed. Cir. 1986) ("Because the district court did not rule on Gore's asserted alternative bases for dismissal … we cannot and will not engage in the fact-finding necessary to rule on them").

However, should the Court decide to entertain Novozymes' arguments, they should be squarely rejected. As explained below, here, Novozymes' written description, enablement, and obviousness defenses turn on sharply disputed facts, rendering summary judgment improper. *See* A1754-76 (S.J. Opp'n at 95-117) (collecting record in support of non-obviousness); A1794-803 (*id.* at 135-44) (addressing certain written description claims); A1811-17 (*id.* at 152-58) (same); *see also* A5581-87 (S.J. Mem. at 66-72) (moving for summary judgment against Novozymes' enablement defenses). Moreover, U.S. Water's strong evidence of objective indicia of non-obviousness must be factored into any dispositive analysis. *See infra* Part II.B.2.

A. Novozymes has produced insufficient evidence in support of its enablement and written description defenses, and the evidence it has produced is disputed.

Novozymes asks this Court to find that claims reciting "reducing the formation of insoluble deposits" and "a pH of 4.5 or higher" are neither described nor enabled. Br. at 49-52. In so pressing, Novozymes ignores both the relevant legal standards and the record, which is rife with factual disputes.

1. The patents adequately describe "reducing the formation of insoluble deposits."

The test for written description is whether the invention is adequately described within the "four corners of the specification" as understood by a skilled artisan. *See, e.g.*, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed.

Cir. 2010) (en banc). This is a question of fact. *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014). Indeed, "written description questions are intensely factual, and should be dealt with on a case-by-case basis, without the application of wooden rules." *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 1000 (Fed. Cir. 2000). And as with all invalidity defenses, Novozymes bears the burden of proving that the claims of the patents-in-suit lack adequate written description by clear and convincing evidence. *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1072 (Fed. Cir. 2005).

Despite this burden, Novozymes cites no evidence of how a skilled artisan would have understood the specification at the time of filing. *See* Br. at 49-52. In fact, Novozymes has no such evidence: Dr. Kohl is silent on this issue. *See generally* A1062-235; A1236-340; A3034-112; A3136-51. Novozymes thus is reduced to attorney argument. *See* Br. at 50-52. But attorney argument is no substitute for evidence, and, on this basis alone, Novozymes' argument must be rejected. *Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1353 (Fed. Cir. 2001) ("It is well established that conclusory statements of counsel or a witness that a patent is invalid do not raise a genuine issue of fact.").

Not only that, the record below is replete with evidence that, based on the specification, a skilled artisan *would* understand that the inventors were in possession of the claimed invention. A988-90 (¶¶ 309-12); ’399 patent (3:21-31, 3:32-61, 6:10-40, example 2). Indeed, the specification includes not only a description of the invention, but also discussion of detailed supporting experiments. A990 (¶¶ 311-12); ’137 patent, examples 2-4 (describing, *inter alia*, experiments showing that “[p]hytase can prevent solid deposits of magnesium phosphate salts from forming in various structures in an ethanol plant”). The patents also discuss numerous parameters such as time, temperature, pH and concentration that can be adjusted to prevent formation of deposits. ’399 patent (6:32-7:37); ’137 patent (6:32-7:37); A972-75 (¶¶ 265-73).

Novozymes nonetheless complains that the patents do not describe the kinetics underlying fouling. Br. at 50. But a patent need not describe the mechanism by which an invention works. *Application of Bowden*, 183 F.2d 115, 119 (C.C.P.A. 1950) (“Under the law a patent will be issued to an inventor although he may not understand the principle upon which his invention works.”) (citing *In re Parlanti et al.*, 158 F.2d 1018 (C.C.P.A. 1947)).

2. The patents adequately describe the reduction of deposits at a pH of 4.5 or higher.

Novozymes next asserts (at 50) that U.S. Water “has previously admitted” that its patents do not describe using a pH of 4.5 or higher. Not so. U.S. Water has explained chapter-and-verse why one of ordinary skill would recognize that the specification contains a description of a process for using phytase to reduce the formation of deposits in which the pH of the fluid in the beer column is 4.5 or higher. *See* A958-64 (¶¶ 219-38).

Specifically, in the ’399 and ’137 patents, the inventors described the problem that their invention solved: “[e]thanol producers have found scale deposits on processing equipment at several stages of ethanol processing …. The deposits tend to be most severe or tenacious on hot surfaces, and where the pH of the processing liquid is highest (about 4.5) ….” ’399 patent (1:34-40); *see also* A959 (¶ 223). As Mr. Simms notes: “[t]he above passage makes clear that the inventors were concerned with deposits that impede heat transfer and flow, and that such deposits are found in areas where there are hot surfaces that have a pH of 4.5.” A960 (¶ 224); *see also* A960-63 (¶¶ 225-26, 233); ’399 patent (1:34-43). In fact, experiments reported in “Table 1 … looked at solubility of magnesium phytate over a range of pH values—all but one of which are above 4.5, ranging from 4.52 to 5.76, and two of which are just incrementally higher than 4.5, i.e., 4.52 and 4.53.” A962 (¶ 231). Based on this information, “one of ordinary skill recognizes that the inventors were concerned with pH values of 4.5 … and higher.” A962 (¶ 231). And, moreover, a skilled artisan would understand this pH of 4.5 or higher could apply to fluid in the beer column. A960-64 (¶¶ 225-38); ’399 patent (3:31-41, 4:14-24, 4:29-47, Tbls. 1, 2, & 4, examples 1, 2 & 4).

Mr. Simms's interpretation of the specification is buttressed by the understanding of persons of skill in the art. Namely, "[i]t is well known among persons skilled in the art that fuel ethanol plants typically try to maintain the liquid going into the … beer column at a cutoff of pH 4.5 or below in order to reduce fouling." A963 (¶ 235). "This typically involves the addition of an acid … to the beer feed to the beer mash heat exchanger and beer column to reduce the pH to 4.5 or below." *Id*. "Table 2 makes clear that the inventors contemplated employing a pH in the … beer column of 4.5 and above if phytase were added to effect a reduction in fouling." *Id*.

3. Novozymes impermissibly strays beyond the four corners of the specification.

Absent adequate support, Novozymes resorts to speculation about trade secrets and purported evidence regarding the timing of plant trials. Br. at 50-51. Novozymes cites to Dr. Young's deposition in an effort to prove that the inventors did not conceive of or test their claimed methods in an ethanol planet prior to filing. Br. at 51. On this basis, Novozymes posits, the inventors could not have adequately described their invention because "one cannot describe what one has not conceived." Br. at 51.

Novozymes' argument runs contrary to well-settled law holding that one need not perform field experiments in order to have a valid patent. *See Alcon Research*, 745 F.3d at 1190-91 ("There is no requirement that the disclosure contain either examples or an actual reduction to practice; rather, the critical inquiry is whether the patentee has provided a description that in a definite way identifies the claimed invention in sufficient detail that a person of ordinary skill would understand that the inventor was in possession of it at the time of filing.”). Again, written description turns on the adequacy of the disclosure in the specification, which Novozymes addresses nowhere in its brief. *Ariad Pharms.*, 598 F.3d at 1351; *Alcon Research*, 745 F.3d at 1190-91. And Novozymes omits that Dr. Young further testified that his extensive experimental work—which is recorded in the patent specification—made clear that the invention reduced deposits. A417-18 (208:17-210:12); A412-18 (189:23-210:12).

4. Novozymes fails to adduce evidence of lack of enablement.

Novozymes' nonenablement argument is equally unsupported because it bypasses the *sine qua non* of nonenablement: whether undue experimentation is required. ”Invalidity for lack of enablement is a conclusion of law and must be supported by facts proved by clear and convincing evidence ….” *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990). It "'is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.'" *Celphalon, Inc. v. Watson Pharms. Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013) (quoting *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010)). These considerations turn on whether experimentation is "routine" or "undue," as assessed using the *In re Wands* factors. 858 F.2d 731 (Fed. Cir. 1988). These factors include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* at 737 (citation omitted).

Novozymes' expert Dr. Kohl failed to consider these factors in his opinions. A5581-87 (S.J. Mem. at 66-72) (addressing the legal insufficiency of Dr. Kohl's opinions). And Novozymes adduces no other evidence. *See* Br. at 49-52. In situations like this, where no competent evidence is offered, *Alcon Research* makes clear that nonenablement cannot be found as a matter of law. *See* 745 F.3d at 1189-90 ("Barr proffered no evidence that any experimentation, let alone undue experimentation, … would be necessary in order to practice the claimed invention. Without that evidence, there is no foundation for the district court's nonenablement ruling.…").

B. Novozymes' obviousness argument similarly rests on sharply disputed issues of fact.

Novozymes also asks this Court to affirm the ruling below on the alternative ground of obviousness. Br. at 52-56. In pressing this position, Novozymes mischaracterizes the record, which is again disputed.

Although obviousness is a question of law, it is highly fact specific, *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1343 (Fed. Cir. 2008), and is assessed using the four guideposts articulated by the Supreme Court in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966): (1) the level of ordinary skill in the art; (2) the scope and content of the prior art; (3) the differences between the prior art and the claims in dispute; and (4) any objective evidence of nonobviousness, including the so-called secondary considerations. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Where genuine disputes about these underlying inquiries are present, summary judgment is improper. *TriMed, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1341-43 (Fed. Cir. 2010).

Here, the factual underpinnings of at least three of these factors—the scope and content of the prior art, the differences between that art and the claimed inventions, and the objective evidence of nonobviousness—are all contested.

1. The scope and content of the prior art, and the differences between the prior art and claimed invention, both turn on disputed material facts.

The lynchpin of Novozymes' obviousness case is its claim that, unlike Veit and Antrim, Caransa expressly teaches reduction in deposits. Br. at 52-53. U.S. Water's experts disagree. A943 (¶¶ 182-83); A1032-35 (¶¶ 417-25); A1039-41 (¶¶ 437-41); A1054-55 (¶¶ 477-78); A846 (¶ 28); A850 (¶ 39). First, Novozymes asserts that "U.S. Water does not challenge the district court's finding that all of the steps of its claimed methods, save the result, are expressly disclosed in Veit and Antrim." Br. at 52. This is incorrect. Deposit reduction is not merely a result; *it is an element of the claims*. Indeed, independent claims 1, 2, 25, and 34 of the '399 patent all require that the claimed addition of phytase "causes a reduction of the formation of insoluble deposits of phytic acid and/or salts of phytic acid in a piece of heat transfer equipment in the plant." Claim 1 of the '137 patent likewise recites that the addition of phytase "reduc[es] the formation of deposits of insoluble phytic acid or phytic acid salts on surfaces in the [fuel ethanol] equipment."

Novozymes has admitted that Veit and Antrim do not expressly disclose deposit reduction. *See, e.g.*, A1531 ("Veit and Antrim Each Expressly Teach All of the Elements Except 'Deposit Reduction'"); A1534 ("The only aspect of the claim that Veit and Antrim do not expressly teach is the result of 'reducing the formation of deposits of insoluble phytic acid or phytic acid salts.'").[8] Novozymes, however, argues that Caransa fills in this missing element. Br. at 53.[9]

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[8] In its brief, Novozymes questions the basis for U.S. Water's assertion that Novozymes has admitted that Veit and Antrim do not disclose deposit reduction. Br. at 48 n.16. As clear above, U.S. Water's statement is well-founded.

[9] Caransa was before the examiner during prosecution of both patents-in-suit, as were Veit and Antrim; the patents nonetheless issued. '137 patent, at 1, "References Cited"; '399 patent, at 1.

But, Caransa has nothing to do with producing fuel ethanol; it discloses a process for producing corn steep liquor ("CSL" or "liquor") from corn in which the corn is milled while it is wet. A1032-33 (¶ 419). Making corn steep liquor is not the same as making fuel ethanol, which is not addressed in Caransa. A1032-33 (¶ 419); A886 (¶ 28); A850 (¶ 39). Indeed, Caransa is wholly silent regarding deposit formation in heat transfer equipment or beer columns of fuel ethanol plants, as claimed in the patents-in-suit. A1032-33 (¶ 419); A886 (¶ 28); A850 (¶ 39); *see generally* Caransa. It does not teach that phytic acid and phytate salts are responsible for deposits, or that phytases may reduce the formation of such deposits in fuel ethanol production. A1032-33 (¶¶ 419-21); A886 (¶ 28); A850 (¶ 39); Caransa (3:40-43).

Novozymes likens "wet milling" in the context of CSL with "wet milling" in the context of fuel ethanol production. Br. at 53. This comparison is misplaced. As Mr. Simms explained, "in fermentation in a wet milling plant, the phytic acid concentration is very low, even if the CSL is not treated with phytase." A1033-34 (¶ 422). "As a result, wet milling fuel ethanol plants do not observe problems with phytic acid/phytate deposit formation." *Id*. Caransa thus suggests nothing about deposit control in fuel ethanol plants to a skilled artisan. A1032-33 (¶ 419); A886 (¶ 28); A850 (¶ 39); *see generally* Caransa.

Novozymes nonetheless argues that Caransa notes formation of a "sludge" or "precipitate coating" in the fermenter following sterilization. Br. at 54. This, Novozymes claims, is proof that Caransa teaches using phytase to prevent fouling. *Id.* Mr. Simms, as one of skill in the art, disagrees: a "sludge" or "precipitate coating" is not a phytic acid deposit; it is "a loose, non-adherent material." A1034-35 (¶ 423). The Caransa "precipitate coating" in wet milling of CSL is thus not equivalent to the phytic acid deposits observed in heat transfer equipment in a fuel ethanol plant. *Id*. And, according to Mr. Simms, "one of ordinary skill in the art would not consider any results reported by Caransa to be predictive of results that would occur in a fuel ethanol plant." *Id*.[10]

Moreover, to prove obviousness, Novozymes must show that "there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. "[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id*. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Novozymes offers none, providing no evidence to support that one of ordinary skill would look to Caransa—which addresses only CSL—to solve the longstanding problem of deposits in fuel ethanol plants.[11]

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[10] Novozymes cites a snippet of Dr. Young's testimony, namely, testimony that the patents-in-suit encompass both wet milling and dry milling. Br. at 54. Novozymes' reliance is misplaced. In truth, Dr. Young was clear that wet milling *corn steep liquor* (as in Caransa) is distinct from wet milling *fuel ethanol*. *See* A395 (118:9-119:4). The testimony accordingly does not support Novozymes' defense.

2. Novozymes overlooks objective evidence of nonobviousness.

Finally, Novozymes concedes that U.S. Water adduced objective evidence of non-obviousness in opposing Novozymes' motion for summary judgment below. Br. at 55. Indeed, at summary judgment, U.S. Water chronicled far-reaching evidence of, *inter alia*, (1) copying; (2) long-felt need; (3) failure by others; (4) skepticism; (5) unexpected results; (6) industry praise; (7) commercial success; and (8) licensing. A1765-76 (S.J. Opp'n at 106-17) (collecting objective evidence). This objective evidence creates additional material factual disputes, precluding summary judgment. *See, e.g., Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1574 (Fed. Cir. 1996); *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1274 (Fed. Cir. 1991); *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378-79 (Fed. Cir. 2012).

As it did in the district court, Novozymes brushes aside this record, arguing that the Court need not even bother with U.S. Water's evidence because

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[11] Indeed, given that prior to the patents-in-suit, the composition of these deposits was not even known (*see* U.S. Water Br. at 4, 9-10), there could be no reasonable expectation that Caransa's process for reducing sludge in wet milling corn steep liquor could successfully solve the problem of intractable deposits on heat transfer equipment in fuel ethanol plants.

Novozymes' own showing of obviousness is so "strong." Br. at 56. This Court has repeatedly admonished that such evidence is extremely probative of obviousness and must be considered.[12] In fact, objective indicia "are crucial in avoiding the trap of hindsight," *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013), and "serve a particularly important role in a case, like this one, where there is a battle of scientific experts regarding the obviousness of the invention." *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1370 (Fed. Cir. 2012). Novozymes' failure even to address this evidence—both here and at the district court—is fatal to its obviousness challenge.

RESPONSE ON CROSS-APPEAL

I. Statement of Issues.

Novozymes' accusations of fraud center on undisclosed documents related to a limitation recited only in the parent '244 patent and not in the patents-in-suit. When that limitation was removed during prosecution of the patents-in-suit, it was called to the attention of the examiner, both by the patent prosecutor and a third party. And the relevant prior art was disclosed to and considered by the examiner.

[12] *See, e.g., Ortho–McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008); *Süd-Chemie., Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1008 (Fed. Cir. 2009); *Knoll Pharm. Co. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004); *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997).

Under these circumstances, did the district court correctly grant summary judgment of no inequitable conduct?

II. Statement of the Case.

A. The U.S. Water patents.

Between 2011 and 2014, the PTO issued three patents that generally claim methods of reducing the formation of insoluble deposits of phytic acid and salts of phytic acid in fuel ethanol processing equipment by addition of a phytase enzyme. ’244 patent; ’137 patent; ’399 patent. The named inventors on each of these patents are Dr. Paul Young and Mr. Roy Johnson and the patents are assigned to U.S. Water. Dr. Mark Skoog of Merchant & Gould P.C. was the attorney who prosecuted the patents. A1845 (20:3-6). And PTO examiner Kade Ariani reviewed and issued each of the three patents. ’244 patent, cover page; ’137 patent, cover page; ’399 patent, cover page. The ’244 patent, which was the first patent to issue, is not asserted in this litigation.

These three patents share a common specification. *Compare* ’244 patent, specification, *with* ’137 patent, specification, *and* ’399 patent, specification. That specification describes adding phytase before, during, or after fermentation, including, for example, the following passage:

> In an embodiment, phytase is added to ethanol processing equipment and/or processing fluid at a time point and under conditions required for the particular type of equipment or stage of ethanol processing. In an aspect,

> phytase is added *to fermentation fluid* to reduce formation of insoluble deposits in downstream ethanol processing equipment. In another aspect, phytase is added to ethanol processing fluids *downstream of the fermentation* process, such as, for example, beer, whole stillage, thin stillage, backset, centrate, or a mixture of these fluids….

’137 patent (6:10-20); ’244 patent (6:6-15); ’399 patent (6:10-20) (emphasis added). Consistent with the above, while certain claims are limited to the addition of phytase *post*-fermentation (e.g., the claims of the ’244 patent), other claims are not so restricted, and cover the addition of phytase at other points in the ethanol production process (e.g., ’137 patent, claim 1; ’399 patent, claim 1). This latter group comprise the claims at issue in this litigation.

B. The prosecution of the ’244 patent.

During prosecution of the first issued patent, the ’244 patent, the initial proposed independent claims were limited to the embodiment in which phytase is added to “ethanol-processing fluids after fermentation.” A2081-84. Subsequently, the applicants amended the proposed claims in the ’244 patent application to specify adding phytase to two specific ethanol processing fluids that occur after fermentation, i.e., “thin stillage, backset, or mixture thereof.” A2222-26.

1. Veit and Caransa.

At issue in this cross-appeal are two prior art references, Veit and Caransa, first distinguished during the ’244 patent prosecution. In response to an obviousness objection, the Applicants distinguished Veit from certain pending claims. A2228-29. These proposed claims recited the addition of phytase to "thin stillage, backset, or mixture thereof," that is, *after* fermentation. A2222-26. The Applicants noted in Veit "the phytase is added before fermentation to benefit fermentation." A2228-29. Based on this difference, the Applicants suggested that Veit and the other cited references, "neither teach nor suggest the presently claimed methods." A2229.

In response to a different obviousness rejection, the Applicants distinguished Caransa over the then-proposed claims, which also recited adding phytase post-fermentation. A2309-17. The Applicants also noted that Caransa related to the making of CSL, which does not involve either thin stillage or backset. A2314-16; *see also* A2318-21. Given these differences, the Applicants argued that Caransa alongside the other cited references "neither teach nor suggest the presently claimed methods." A2316.

The '244 patent issued on October 18, 2011, with claims that recited "thin stillage, backset, or mixture thereof." '244 patent.

C. The prosecution of the patents-in-suit.

While all the patents share a common specification, the claims of the issued patents differ. *Compare* '244 patent, claim 1, *with* '137 patent, claim 1, *and* '399 patent, claim 1. One relevant difference is that the claims of the patents-in-suit are not limited to the addition of phytase to "thin stillage, backset, or mixture thereof," as clear from both the claims themselves and the prosecution history. *See* '137 patent, claim 1; '399 patent, claim 1. This distinction was called to the attention of the examiner in a July 23, 2012 amendment filed during the '137 patent prosecution. A2545. In that amendment, the Applicants depicted for the examiner exactly how the then-pending claims compared to claim 1 of the '244 patent, including the absence of the "thin stillage" limitation (A2545):

> Applicants submit that the newly presented claims are supported by the specification as filed. The two new independent claims, claims 39 and 40, are generally patterned on issued independent claim 1 of U.S. Patent No. 8,039,244 (the '244 patent). The similarity of these two independent claims to claim 1 of the '244 patent is illustrated below by showing these newly presented claims as though they were prepared by amending the first independent claim of the '244 patent:
>
> 39. A method of reducing formation of insoluble deposits of phytic acid or salts of phytic acid in a ~~food or~~ fuel ethanol-processing equipment ~~that contacts thin stillage, backset, or mixtures thereof~~, the method comprising:
>
> adding phytase to an ethanol processing fluid in the plant ~~said thin stillage, backset, or mixture thereof~~ containing phytic acid or salts of phytic acid under conditions suitable for converting the insoluble phytic acid or phytic acid salts to soluble products; thereby reducing the formation of deposits of insoluble phytic acid or phytic acid salts in the equipment;
>
> wherein the reduction in the formation of deposits of insoluble phytic acid or phytic acid salts in the equipment is accomplished substantially without the addition of an acid.
>
> 40. A method of reducing formation of insoluble deposits of phytic acid or salts of phytic acid in a ~~food or~~ fuel ethanol-processing equipment ~~that contacts thin stillage, backset, or mixtures thereof~~, the method comprising:
>
> adding phytase to an ethanol processing fluid in the plant ~~said thin stillage, backset, or mixture thereof~~ containing phytic acid or salts of phytic acid under conditions suitable for converting the insoluble phytic acid or phytic acid salts to soluble products; thereby reducing the formation of deposits of insoluble phytic acid or phytic acid salts in the equipment;
>
> wherein the pH of the ethanol processing fluid in a beer column is 4.5 or higher during production of ethanol.

As seen above, by striking through the phrase "thin stillage, backset, or mixtures thereof" and replacing that term with the generic "ethanol processing fluid in the plant" in each of the claims, the Applicants made clear to the examiner that the new claims were not restricted to adding phytase after fermentation. A2545.

This distinction was also pointed out to the examiner during prosecution of the '399 patent, in a third-party submission. A5046-68; A5399-404. The third party asserted that, unlike the '244 patent, the claims of (what became) the '399 patent were not limited by where the phytase could be added. A5046-68; A5399-404:[13]

> The claims of the '244 patent recite adding phytase to ethanol processing fluids with narrow limitations to the type of fluid to which the phytase is added. The claims in the present application recite adding phytase to ethanol processing fluids with no further limitation to the type of fluid to which the phytase is added.

A5051-52; *see also* A5051 ('244 patent claims addition of phytase to "thin stillage, backset"); A5060 (noting that the pending claims were not limited as to at which point in ethanol processing phytase was added). The examiner indicated in the file history that she reviewed the art in this third-party submission. A5399-404. This prior art included both Veit and Caransa. A5403.

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[13] In the initial "Summary," the submission further acknowledged that "[the] present application … is a continuation of [the '244 patent]," and that "[t]he claims in the present application recite adding phytase to ethanol processing fluids with no further limitation to the type of fluid to which the phytase is added." A5048.

D. The issued claims of the patents-in-suit.

Following further prosecution and amendment, proposed claim 40 (copied above) issued on April 9, 2013, as claim 1 of the ’137 patent. *Compare* A2541 (claim 40), *with* ’137 patent (12:30-42). Claim 39 (above) issued in a separate continuation application, following additional prosecution and amendments, as claim 1 of the ’399 patent on December 17, 2013. *Compare* A2541 (claim 39), *with* ’399 patent (12:30-57). Beyond substituting “thin stillage, backset, or mixtures thereof” with “ethanol processing fluid in the plant,” these issued claims recite additional limitations that are materially different than the ’244 patent claims. ’399 patent, all claims; ’137 patent, all claims.

To illustrate, claim 1 of the ’137 patent added limitations relating to reducing the formation of deposits of phytic acid and phytic acid salts on the surfaces of a beer column and wherein the pH of the ethanol processing fluid is 4.5 or higher during production of ethanol. *Compare* ’244 patent (12:5-15), *with* ’137 patent (12:30-42). Similarly, claim 1 of the ’399 patent added limitations relating to reducing the formation of deposits of phytic acid and phytic acid salts on the surfaces of a piece of heat transfer equipment and wherein the reduction in the formation of such deposits is accomplished substantially without the addition of an acid in the presence of an oxidizer, oxidizing agent or UV light. *Compare* ’244 patent (12:5-15), *with* ’399 patent (12:30-57).

E. The *ChemTreat* litigation.

In April 2011, while prosecution of the ’244 patent (the first patent to issue) was ongoing, U.S. Water brought a misappropriation of trade secrets action against ChemTreat in the District of Minnesota. A4889-93. Six months later, on October 18, 2011 (the date the ’244 patent issued), ChemTreat—*not U.S. Water*—sought leave to file declaratory judgment counterclaims of non-infringement and invalidity of the ’244 patent, which U.S. Water opposed for lack of case or controversy, having never asserted or threatened to assert the ’244 patent against ChemTreat. A4895-900. The Minnesota court granted ChemTreat’s motion on April 4, 2012. A4896.

Shortly thereafter, on May 10, 2012, U.S. Water and ChemTreat reached a settlement regarding the trade secret claims, stipulating to dismissal. A4902. ChemTreat’s patent counterclaims, however, were not included. *Id.* Accordingly, on July 2, 2012, ChemTreat moved for summary judgment of noninfringement on the grounds that it did not add phytase to “thin stillage” or “backset,” as recited in the ’244 patent; rather, ChemTreat added the phytase prior to fermentation. A4898; A4904-05. U.S. Water responded, first, by arguing that the court lacked jurisdiction, given the lack of case or controversy; and, second, by arguing that claim construction of the ’244 patent and discovery were required prior to a patent infringement determination. A2926-42. More specifically, U.S. Water posited that "when phytase is added to backset, and the backset (containing phytase) is circulated back into fermentation, the method ChemTreat teaches its customers may indeed infringe the '244 patent" under the doctrine of equivalents. A2941. Patent prosecutor Dr. Mark Skoog submitted a declaration to support this opposition (A3281-86), explaining that "adding phytase to backset as it is being recycled back into fermentation," as ChemTreat practiced, "is equivalent to pouring the bucket of phytase into the fermenter, as long as the phytase in the backset is effective to reduce deposits of phytic acid salts downstream of the fermenter." A3284 (¶ 15). U.S. Water thus requested the court hold off on summary judgment to permit discovery on these issues. A2942-46. The Minnesota court agreed to allow U.S. Water time for additional discovery, and denied ChemTreat's motion without prejudice. A4897; A4907-17.

ChemTreat subsequently renewed its motion for summary judgment of noninfringement. A4897; A4919-20. U.S. Water did not oppose the motion on the merits; rather, after discovery, U.S. Water renewed its jurisdictional arguments. A4897; A4922-29. On January 16, 2013, the Minnesota court found it had subject matter jurisdiction and granted summary judgment of noninfringement. A4897-99. The court's summary judgment order is based only on its construction of "to said thin stillage, backset, or mixtures thereof," as recited in the '244 patent, based on the specification, claims, and file history. A4898; '244 patent (12:5-15, 12:50-51, 13:8-9); A1352-53. Based on the record before it, the Minnesota court construed that limitation to require that the phytase be added after fermentation. A4898-99. Since ChemTreat allegedly taught its customers to add its phytase product either before or during fermentation, the court found that ChemTreat did not infringe the ’244 patent. A4898.

F. The *ChemTreat* court did not consider the claims, relevant specification portions, or prosecution histories of the patents-in-suit.

The *ChemTreat* court considered neither the claims nor the prosecution history of the ’137 and ’399 patents asserted in this suit. A4898-99. Indeed, neither patent had issued at that time. ’137 patent & ’399 patent; A4895-900. Nor, given the narrow language of the ’244 patent claims, did the court consider the broad language in the shared specification describing the addition of phytase at various points in the ethanol process. A4898-99; ’244 patent (6:6-15). Moreover, dicta from the court’s summary judgment hearing (quoted at length by Novozymes at 20) was *not* included in the court’s order. A4895-900.

G. Issuance of the patents-in-suit.

After the Minnesota court’s order, the examiner issued the patents-in-suit. ’137 patent & ’399 patent. The phrase construed by the Minnesota court—“thin stillage, backset, or mixtures thereof”—is not recited in *any* of the issued independent claims. *See* ’137 patent, claims; ’399 patent, claims. Indeed, the only claim of the ’137 patent that even mentions “thin stillage” and “backset” is unasserted dependent claim 5. ’137 patent, claim 5. None of the ’399 patent claims recites “thin stillage” or “backset.” ’399 patent, claims.

H. Novozymes’ inequitable conduct allegations.

On December 17, 2013, U.S. Water filed the present infringement action asserting the ’137 patent, amending to add the ’399 patent thereafter. A225; A153. Almost a year later, on November 14, 2014, Novozymes amended its counterclaims to include fraud allegations. A233. Less than two weeks later, Novozymes again requested leave to amend. *See* A4879-80; A4881-87. Although the district court granted Novozymes’ motion, it made clear that additional amendments must clear a high hurdle: “This will be the second time that Novozymes has tweaked its position in this case: subsequent efforts to do so will require a very persuasive showing.” A4886.

Novozymes’ alleged that “the applicants” and their patent prosecution attorney Dr. Mark Skoog did not disclose certain materials from the *ChemTreat* litigation during the prosecution. *See* A572-78 (¶¶ 81-97). Specifically, Novozymes alleged that the applicants and Attorney Skoog should have disclosed nine documents:

> The specific documents the applicants and Attorney Skoog failed disclose to the PTO during prosecution of the ’137 and ’399 patent applications include, at least: (1) defendant ChemTreat’s motion for summary judgment

> dated July 2, 2012 and related exhibits; (2) U.S. Water's opposition to summary judgment dated July 27, 2012; (3)–(4) Attorney Skoog's declarations relied upon for U.S. Water's "equivalents" arguments; (5) defendant ChemTreat's reply to U.S. Water's opposition to summary judgment; (6) the August 17, 2012 hearing transcript in which Judge Schiltz made several material statements about prosecution history estoppel; (7) Attorney Skoog's deposition transcript from the ChemTreat litigation; (8) defendant ChemTreat's renewed motion for summary judgment dated December 23, 2012; and (9) the Minnesota court's order granting summary judgment against U.S. Water dated January 16, 2013.

A574 (¶ 86); *see also* A575 (¶ 90). Had the examiner been aware of the arguments made in these nine documents related to the '244 patent's scope, Novozymes claimed, she would not have issued the patents-in-suit. A572-75 (¶¶ 81-85, 90).

Novozymes did not accuse U.S. Water's CEO Al Bly of any misconduct; his name is nowhere mentioned. *See* A559-78 (¶¶ 45-97). Nor did Novozymes allege that anyone engaged in fraud by failing to disclose certain U.S. Water's trade secrets, in particular, any alleged trade secrets related to the benefits of acid reduction and/or employing a pH of 4.5 or higher. *See* A559-78 (¶¶ 45-97); A574 (¶ 86).

I. The district court's summary judgment order.

On January 16, 2015, U.S. Water moved for summary judgment of no inequitable conduct. On July 29, 2015, the district court granted that motion, concluding that Novozymes had "failed to adduce evidence sufficient to establish either materiality or deceptive intent." A36 (Order at 35).

First, the district court rejected Novozymes' claim that the *ChemTreat* materials were "but-for" material to patentability. The district court concluded that the July 23, 2012 amendment "set out the amended claim with differences with claim 1 of the '244 patent highlighted." A34 (Order at 33). It therefore followed, concluded the district court, that "[i]t would have been amply clear to the examiner that the patentees were seeking a claim that was broader in a sense that the after-fermentation limitation was removed." *Id.* Moreover, the third-party submission (and the examiner's confirmed evaluation thereof) made clear "that the examiner knew she had to evaluate the allowability of the broader claims over the prior art, particularly Veit and Caransa." A35 (Order at 34). The examiner was thus "fully aware that the broader claims had to be examined over Veit and Caransa, and a general allegation that the examiner did not pay attention to what was put before her is not enough to sustain an allegation of inequitable conduct." *Id.* (citing *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000) ("[A]n applicant is not required to tell the PTO twice about the same prior art.")). The district court therefore concluded that "[o]n this record, there is simply no evidence that information about the arguments made during the *ChemTreat* litigation, or any decision from the *ChemTreat* court, would have had any impact on the claims of the patents-in-suit." *Id.*

Regarding intent, the district court found Novozymes' evidence insufficient. Novozymes had presented evidence that "the patentees recognized the benefits of securing broader claims," but the district court found this unremarkable: "the desire to secure broader claims in a continuation is an utterly routine situation in patent prosecution." A35 (Order at 34); *see also N. Telecom, Inc.*, 908 F.2d at 939 (Thus, "[g]iven the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required."); *id.* ("A patentee's oversights are easily magnified out of proportion by one accused of infringement.") (citation omitted). And "U.S. Water's arguments to the [PTO] about the content of the prior art, when that prior art was before the examiner," cannot be the basis for an inequitable conduct finding. A35-36 (Order at 34-35).

III. Summary of Argument on Cross-Appeal.

The district court correctly granted summary judgment of no inequitable conduct because Novozymes "failed to adduce evidence sufficient to establish either materiality or deceptive intent." A36 (Order at 35).

First, Novozymes cannot show that "but-for" the non-disclosure of the *ChemTreat* documents the patents-in-suit would not have issued. The examiner was made aware of the differences between the ’244 patents and pending claims of the continuation applications by both the applicants and a third party. The examiner was also made aware of the relevant prior art. With full knowledge of the differences between the old and new claims, she issued the patents-in-suit. Novozymes fails to explain how, under these circumstances, statements from the *ChemTreat* litigation regarding the scope of the ’244 patent claims related to limitations not recited in the patents-in-suit would have impacted that decision. And while Novozymes endeavors to supplement its counterclaim with new bases based on allegations that “U.S. Water” withheld trade secret information, these theories, which were not raised in the district court, have been waived.

Second, even if “but-for” materiality was established, Novozymes has adduced no evidence of specific intent to deceive the PTO. Novozymes speculates based on a combination of knowledge of the *ChemTreat* litigation coupled with no disclosure that deceptive intent can be inferred. But this is insufficient as a matter of law. And while Novozymes again offers newly concocted theories of fraud—here, that U.S. Water CEO Al Bly defrauded the PTO—these theories were not pled and, in any event, were waived.

IV. Argument on Cross-Appeal.

A. Standard of review.

"The grant of summary judgment receives plenary review, applying the same standard as did the district court." *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1319 (Fed. Cir. 2010) (citing *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1378 (Fed. Cir. 2008)). Under that standard, summary judgment of no inequitable conduct is appropriate when, "drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant cannot prevail." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed. Cir. 1998). In other words, "[w]hen a party has failed to introduce evidence sufficient to establish the existence of an essential element of that party's case in accordance with the applicable standard of proof, summary judgment is properly granted against that party." *Optium Corp.*, 603 F.3d at 1319-20 (citations omitted).

B. Novozymes was required to adduce clear and convincing evidence of both materiality and intent to deceive.

The defense of inequitable conduct requires a threshold showing both that "the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO]." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008) (alteration in original, citations omitted). These are independent elements. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649

F.3d 1276, 1290 (Fed. Cir. 2011) (en banc). To withstand U.S. Water's motion, Novozymes was required to adduce evidence from which the trier of fact could find both requirements by clear and convincing evidence. *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1379 (Fed. Cir. 2002). As this Court has noted, a "patentee's oversights are easily magnified out of proportion by one accused of infringement." *N. Telecom, Inc.*, 908 F.2d at 939 (citation omitted). Thus, "[g]iven the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required." *Id.* And failure to marshal this clear and convincing support for either materiality or intent requires summary judgment. *AstraZeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583 F.3d 766, 777 (Fed. Cir. 2009). As recognized by the district court, Novozymes failed on both accounts.

C. Novozymes offers no evidence of "but-for" materiality.

1. There is no evidence supporting the materiality of the *ChemTreat* documents.

First, Novozymes challenges the district court's holding that "[o]n this record, there is simply no evidence that information about the arguments made during the *ChemTreat* litigation, or any decision from the *ChemTreat* court, would have had any impact on the claims of the patents-in-suit." A35 (Order 34); Br. at 63-65. Novozymes' argument reduces to the notion that, even though the examiner was given a comparison of the ’244 patent claims with the newly proposed claims, and even though the examiner was made aware by a third party that the applicants sought “broader” claims, and even though the examiner was aware of both Veit and Caransa, there somehow nonetheless remains “at least a question on whether the patents would have issued.” Br. at 64-65.

This argument does not pass muster. A showing of inequitable conduct is not satisfied with a “question of whether the patents would have issued.” It requires clear and convincing evidence of “but-for” materiality. *Therasense*, 649 F.3d at 1291. That is, Novozymes was required to come forward with clear and convincing evidence that “but-for” the non-disclosure of the *ChemTreat* information, the examiner would not have allowed the claims. *Id*. It did not. Instead, Novozymes summarily declares that “U.S. Water’s litigation position … renders at least Veit and Caransa invalidating prior art.” Br. at 64 (citing *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987)). Of course, “U.S. Water’s litigation position” would not render a claim invalid: invalidity is determined through a comparison of the prior art—here, Caransa and Veit—to the claims *as issued*. Novozymes’ breezy treatment sidesteps this inquiry. Novozymes omits even a cursory discussion of the legal basis under which the claims would have been rejected.

The bottom line is that the examiner was well aware of both Caransa and Veit; the examiner considered these references, U.S. Water and third parties both directed the examiner to the differences between the pending claims of the patents-in-suit and the ’244 patent, and the examiner nonetheless issued the claims. A34-35 (Order 33-34). As acknowledged by the district court, this is fatal to Novozymes’ materiality hypothesis. *See, e.g.*, *Innogenetics*, 512 F.3d at 1379; *see also Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1291 (Fed. Cir. 2012) (litigation documents related to a parent patent were not “but for” material to the child patent).[14]

Faced with the undisputed record, Novozymes retreats to the position that, absent vaguely identified *ChemTreat* dicta, it was “not reasonable to expect that the examiner fully appreciated the significance of U.S. Water’s amendments.” Br. at 65. The issue before the Court is not whether the examiner “fully appreciated” an amendment; it is whether “but-for” the non-disclosure of information the patents would have issued. And, as the district court held, "a general allegation that the examiner did not pay attention to what was put before her is not enough to sustain an allegation of inequitable conduct." A35 (Order at 34) (citing *Fiskars, Inc.*, 221 F.3d at 1327).

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[14] Novozymes further hints that the patents suffer from “disclaimer.” Br. at 58. As explained in U.S. Water’s motion for summary judgment, Novozymes cannot show that U.S. Water disclaimed the addition of phytase at points other than thin stillage or backset. A5532-49; *Regents of Univ. of Minn. v. AGA Med. Corp.*, 717 F.3d 929 (Fed. Cir. 2013). The patents-in-suit have different claim language than the ’244 patent, and their prosecution histories are clear that the claims were not limited to adding phytase after fermentation. A5532-49 (S.J. Mem. at 17-34). Regardless, Novozymes’ fleeting reference to purported disclaimer fails meaningfully to address this claim, and is waived. *C & N Corp. v. Gregory Kane & Ill. River Winery, Inc.*, 756 F.3d 1024, 1026 (7th Cir. 2014).

2. Novozymes' waived theories related to acid reduction and pH also do not meet the "but-for" materiality standard.

Novozymes next claims that "U.S. Water's admission in the *ChemTreat* litigation that reduced acid feed is a trade secret not disclosed in the specification of the parent '244 patent … would have foreclosed allowance of any claims including such a limitation." Br. at 64 (citations omitted). This, a new position, is unmoored to the record and has been waived.

The accusation that U.S. Water withheld the trade secret status of "reduced acid feed" or "pH of 4.5 or higher" from the PTO is nowhere in Novozymes' counterclaim. A559-78 (¶¶ 44-97) (*see especially* ¶ 86 (listing "specific documents the applicants and Attorney Skoog allegedly withheld from the PTO during prosecution")). Novozymes acknowledges as much. *See* Br. at 62 n.18.[15]

[15] While Novozymes cites to evidence it claims supports its new theory, it also concedes this evidence was not before the district court in the inequitable conduct briefing. *See* Br. at 62 n.18. Rather, the evidence was submitted to the district court as part of Novozymes' motion for summary judgment for lack of written description, filed on January 16, 2015, and again as part of a motion for leave to file a sur-reply related to written description, which was not granted. *See* Br. at 62

Having failed to plead it—let alone, plead it with particularity under Rule 9(b)[16]—include it in its summary judgment opposition, or adequately develop it anywhere in the record, the argument is waived. *See, e.g.*, *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1062 (Fed. Cir. 2004); *Novosteel SA v. U.S., Bethlehem Steel Corp.*, 284 F.3d 1261, 1273-74 (Fed. Cir. 2002).[17]

Notwithstanding waiver, Novozymes' "acid reduction" and "pH of 4.5 or higher" charge is unfounded. First and foremost, the patents-in-suit do not claim

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n.18; *see also* A4763-85 (relying on A4638 and A4790); Br. at 24 & 60-61 (citing A3015, A2863, A3029, A3028 (all filed 1/16/15 by Novozymes)).

[16] It is well established that inequitable conduct must be pled with particularity. *See, e.g., Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327-28 (Fed. Cir. 2009) (accused infringer is required to plead inequitable conduct with particularity under Rule 9(b)).

[17] Novozymes claims (Br. at 62 n.18) that "it was not able to fully brief the issue because key evidence had not been produced." Not so. Of the five documents relied on by Novozymes, four were produced prior to summary judgment, as proven by the fact that they were submitted to the district court in January 2016. *See* A3015, A2863, A3029, A3028. Only one—a snippet of Mr. Johnson's June 2015 deposition (A4638 (cited at 62))—post-dates summary judgment. *See also* A4790 (cited by Novozymes at 62 (copying verbatim Mr. Johnson's testimony)). That testimony does nothing to advance Novozymes' cause. Mr. Johnson merely testified—subject to repeated and well-founded objections—that, while the patent specification teaches that one can operate the plant at a higher pH (which one of ordinary skill in the art would understand to allow for acid reduction), whether pHytOUT® was, in fact, "more effective than acid feed" was at the time of *ChemTreat* confidential plant trial data. *See* A4637-39 (134:2-139:13). The trade secret declaration relied on by Novozymes confirms this. A3015 (¶ 13) (whether use of phytase was "more effective than acid feed" was a trade secret confirmed from data taken at plant trials); *see also* A1527 (relying on evidence that plant trials occurred after the patent filing). Moreover, while Novozymes sought to supplement the summary judgment record regarding written description, it made no such request with regard to inequitable conduct.

"acid reduction." They claim, *inter alia*, methods of reducing phytic acid deposits where, among other limitations, "the pH of the ethanol processing fluid in the beer column is 4.5 or higher" ('137 patent, claim 1) or where the method is accomplished "substantially without the addition of an acidic compound … in the presence of an oxidizer, oxidizing agent, or ultraviolet light" ('399 patent, claim 1). Novozymes fails to address precisely how "but-for" the purported non-disclosure of extrinsic information on "reduction in acid feed" these specific claims would not have issued.

Novozymes' belated theory apparently centers on the premise that certain unidentified claims of the patents-in-suit would not have issued under 35 U.S.C. § 112 if the examiner had been made aware of extrinsic information related to whether "reducing acid feed" and "allowing the pH to be 4.5 or higher" were also treated as trade secrets. Br. at 61. Along these lines, Novozymes continues, the examiner would not have issued the claims had she been presented with extrinsic information related to when reduction in acid feed and pH of 4.5 or higher were first realized. *Id.* This position runs counter to law. As noted *supra* Part II.A.1, "[t]he hallmark of written description is disclosure … [T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad Pharms*, 598 F.3d at 1351. Novozymes is silent on the specification, which supports U.S. Waters claims. *See* A958-64 (¶¶

219-38); ’399 patent (1:34-43, 3:32-41, 4:14-24, Tbls. 1, 2 & 4, examples 1 & 2); A970-72 (¶¶ 258-62); ’399 patent (5:21-37) (identifying specification support for both pH and acid limitations in the specification). In issuing the patent, the examiner—based on the specification—found the claims adequately described.

Even assuming, *arguendo*, however, that Novozymes could establish that U.S. Water attempted to claim as a “trade secret” what it also disclosed in the specification (which it has not (*see supra* n.13)), the result would be a finding that U.S. Water is not entitled to trade secret protection. *See On-line Techs. Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1141 (Fed. Cir. 2004); *BondPro Corp. v. Siemens Power Generation, Inc.*, 463 F.3d 702, 706 (7th Cir. 2006); *Conmar Prods. Corp. v. Universal Slide Fastener Co.*, 172 F.2d 150, 155-56 (2d Cir. 1949). In other words, even if Novozymes could show that the asserted trade secrets in the *ChemTreat* case and the asserted patents cover the same subject matter, the patent destroys the secrecy necessary to maintain trade secrets, but the patent remains valid. *See BondPro Corp.*, 463 F.3d at 706.

Not surprisingly, Novozymes fails to muster any precedent in support of its theory. The inapposite cases relied on by Novozymes (Br. at 64-65) merely stand for broad principles, untethered to inequitable conduct, materiality, or the circumstances of this case.[18]

D. The district court correctly held that Novozymes had adduced no evidence of specific intent to deceive the PTO.

Novozymes' arguments with respect to intent to deceive fare even worse. To meet its intent burden, Novozymes must show by clear and convincing evidence that Dr. Young, Mr. Johnson, or Attorney Skoog (1) misrepresented or omitted information material to patentability, and (2) did so with *specific intent* to mislead or deceive the PTO. *Therasense*, 649 F.3d at 1290. That is, it must show that Dr. Young, Mr. Johnson, or Attorney Skoog (1) knew of information, (2) knew that information was material to patentability, and (3) nonetheless made the deliberate decision to withhold that reference from the PTO with the intent to deceive. *Id*. This burden requires proof, not mere speculation: "there must be a factual basis for a finding of deceptive intent." *Abbott Labs.*, 544 F.3d at 1355 (citation omitted). Intent cannot be inferred solely from the fact that information was not disclosed. *Larson Mfg. Co. of S. D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Circ. 2009). Nor can it be inferred based on the alleged materiality of the withheld information[19] or based on negligence—even gross negligence—or poor judgment.[20] And importantly, intent "'must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.'" *Larson Mfg.*, 559 F.3d at 1340 (quoting *Star Scientific*, 537 F.3d at 1366).

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[18] *See* Br. at 64-65 (citing *Anascape, Ltd. v. Nintendo of Am. Inc.*, 601 F.3d 1333, 1335 (Fed. Cir. 2010) ("[t]o obtain the benefit of the filing date of a parent application, the claims of the later-filed application must be supported by the written description in the parent"); *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1379 (Fed. Cir. 2009) ("The written description doctrine prohibits new matter from entering into claim amendments, particularly during the continuation process."); *Atl. Research Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1356 (Fed. Cir. 2011) (affirming ruling that a particular claim was not adequately described, and reasoning that the patentee's protection as a trade secret of the specific embodiment claimed supported this finding); *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1365 (Fed. Cir. 2011) (affirming a finding of invalidity where the inventor retained as a trade secret the best mode for practicing a claim and failed to disclose that mode in the specification)).

Novozymes has fallen well short of clearing this high bar with respect to all three accused individuals—Dr. Young, Attorney Skoog, and Mr. Johnson. First, while Novozymes mentions Dr. Young by name, it fails to cite any record support—or even basis—for its accusation. Br. at 66-68. This is unsurprising, given that Dr. Young was not involved in (and was only vaguely aware of) the *ChemTreat* litigation and had no knowledge of the documents on which Novozymes' fraud claims depend. A424-25 (235:25-236:4, 236:5-10, 237:18-22,

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[19] *Star Scientific*, 537 F.3d at 1366; *Abbott Labs.*, 544 F.3d at 1355-56.

[20] *Abbott Labs.*, 544 F.3d at 1353-54; *Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc.*, 628 F.3d 1359, 1379 (Fed. Cir. 2010).

237:24-238:1, 239:22-240:9, 238:20-239:5); A1967 (345:10-22). Summary judgment as to Dr. Young was thus proper. *See, e.g.*, *Optium Corp.*, 603 F.3d at 1320-22; *AstraZeneca Pharm. LP*, 583 F.3d at 776-77.

As to Attorney Skoog, Novozymes posits that it has shown specific intent to deceive because of purportedly "contradictory" statements made between the *ChemTreat* litigation and the prosecution history.[21] Here, Novozymes attempts to transform an "an utterly routine situation in patent prosecution"—i.e., "[a] desire to secure broader claims in a continuation"—into fraud. A35 (Order at 34). Its attempt utterly fails. Attorney Skoog accurately distinguished the pending claims of the '244 patent from Veit and Caransa, both of which were before the PTO. Later, during the prosecution of the patents-in-suit, he amended the pending claims, making abundantly clear to the examiner that he had removed the "thin stillage, backset, or mixture thereof" limitation. It is not inequitable conduct to take positions before the examiner regarding art that has been disclosed to the examiner. *Innogenetics, N.V.*, 512 F.3d at 1379. And when he later proposed amendments to the claims, Attorney Skoog was under no obligation "to tell the PTO twice about the same art, on pain of loss of the patent for inequitable conduct." *Fiskars, Inc.*, 221 F.3d at 1327. Finally, Novozymes (Br. at 66)

[21] Novozymes adduces no evidence that Attorney Skoog or Dr. Young were aware of the U.S. Water trade secret evidence. *See* Br. at 66-68.

generally relies on Attorney Skoog's failure to disclose the *ChemTreat* documents to the PTO as evidence of intent. This too fails as a matter of law: "nondisclosure, by itself, cannot satisfy the deceptive intent element." *Larson Mfg.*, 559 F.3d at 1340.

Novozymes marshals an equally thin showing against Mr. Johnson. As with Attorney Skoog, Novozymes urges that Mr. Johnson "made representations to the district court in the *ChemTreat* litigation that contradicted the representations the inventors and their attorney had previously made to the [PTO]." Br. at 66. But Novozymes fails to identify any specific representations (let alone contradictory ones) made *by Mr. Johnson* in either the *ChemTreat* litigation or the prosecution history that serve as the basis for this accusation. *See id.* at 16-24, 56-68 (relying on statements made by "U.S. Water," "they," or "the applicants").

Beyond these bald assertions, other than evidence that he attended a *ChemTreat* summary judgment hearing[22] (i.e., knowledge of dicta) and non-disclosure of the *ChemTreat* litigation materials, the only evidence relied on by Novozymes to indict Mr. Johnson is non-disclosure of alleged trade secret information. *See* Br. at 61-62, 66-67. But again, even if such a theory had not been waived (which it has), Novozymes' claim still fails to identify any evidence

[22] In fact, Mr. Johnson was unable to hear the court at this hearing, as confirmed by Mr. Bly, who also attended. A329 (239:2-16, 241:9-13); A2020 (108:17-109:6).

of specific intent to deceive the PTO. Rather, Novozymes merely proffers a theory that Mr. Johnson was aware of a trade secret that was somehow relevant to the prosecution, but did not disclose it to the examiner. This is not enough to prove (as Novozymes must) that Mr. Johnson (1) knew of information, (2) knew that information was material to patentability, and (3) nonetheless made the deliberate decision to withhold that reference from the PTO with the intent to deceive. *Therasense*, 649 F.3d at 1290; *see also 1st Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1376-77 (Fed. Cir. 2012); *AstraZeneca Pharms. L.P.*, 583 F.3d at 776-77.

Ultimately, stripped of vague accusations against U.S. Water generally, the centerpiece of Novozymes' intent theory is the testimony of U.S. Water's CEO Al Bly regarding his purported knowledge of an alleged plot to "obtain patent protection for subject matter that the company had maintained as a trade secret." Br. at 67-68. Novozymes claims that Mr. Bly's "admissions" are not merely probative of intent but "*dispositive*" on the issue. Br. at 67-68 (emphasis added). Setting aside that Novozymes relied on none of this evidence in the district court to oppose summary judgment of no inequitable conduct,[23] and setting aside that the purported *ChemTreat* trade secret scheme has been waived (*see supra* Part

[23] This deposition transcript was filed on June 22, 2015, in conjunction with Novozymes' Motion for Leave to Supplement the Summary Judgment Record Re Novozymes' Motion for Summary Judgment *of No Written Description for the "Ph 4.5 or Higher" Limitation*. As noted *supra* n.15, that motion was not granted.

IV.C.2.), Novozymes' theory still fails because Mr. Bly has not been accused of inequitable conduct in this case. *See* A559-78 (*id.* ¶¶ 45-97); *see Exergen Corp.*, 575 F.3d at 1327-28; *Golden Blount, Inc.*, 365 F.3d at 1062. And the cited testimony sheds no light on the purported intent to deceive of those who actually stand accused—Dr. Young, Attorney Skoog, and Mr. Johnson.[24]

In sum, U.S. Water was entitled to summary judgment of no inequitable conduct, as held by the district court.

CONCLUSION

The judgment of invalidity as to the asserted claims of the patents-in-suit should be reversed and vacated and the judgment of no inequitable conduct should be affirmed.

[24] The testimony is also insufficient to establish specific intent. It merely suggests from a layperson's perspective that U.S. Water had trade secrets; U.S. Water had patents; U.S. Water still has some non-specific trade secrets; and, at some unidentified point, some of those trade secrets "may have … [been] put into patent applications and at that point they wouldn't be trade secrets anymore." A4701-02 (quoted in Br. at 68). Such testimony is not relevant to, let alone "dispositive of," intent to deceive.

DATED: January 28, 2016

Respectfully submitted,

Perkins Coie LLP

s/ Michelle M. Umberger
Michelle M. Umberger

Attorneys for Plaintiffs-Appellants
U.S. Water Services, Inc. and Roy
Johnson

Proof of Service

In accordance with Federal Rule of Appellate Procedure 25 and Federal Circuit Rule 25, I certify that I caused this brief to be served via the Federal Circuit's CM/ECF system on counsel of record for the Defendants-Cross-Appellants.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: January 28, 2016, at Madison, Wisconsin

/s/ *Michelle M. Umberger*
Michelle M. Umberger

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief contains 13,969 words, excluding the portions exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft® Word 2010 and 14-point Times New Roman type.

Dated: January 28, 2016

/s/ *Michelle M. Umberger*
Michelle M. Umberger

Attorney for U.S. Water Services, Inc. and Roy Johnson

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